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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,273	03/01/2004	John W. Hanrahan	MGU-0027	3977

7590 01/29/2007

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EXAMINER	
STANDLEY, STEVEN H	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/790,273	HANRAHAN ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 11/07/06 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 7-8 are under examination. Applicant has canceled claims 1-6.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

Rejection of claim 7-8 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office action dated 8/08/06. Applicant's arguments have been fully considered and not found to be persuasive. While the Examiner appreciates the changes Applicant has made to the claims because the changes address several of the issues pointed out, the issue of tagging an intracellular loop has not been resolved. Applicant argues that the specification enables tagging and labeling the intracellular loop of a membrane protein. While the specification does disclose labeling the intracellular loop of a transmembrane protein by expression of a cytosolic biotin ligase, it is not clear, except if used only as a control, how inserting the biotin tag in an intracellular loop would allow the identification of agents that correct the protein misfolding, because among the available options tagging the intracellular domain would result in either all of the mutant protein being labeled

regardless of localization (cytosolic biotin ligase), or none of it labeled (ER localized, secretory, or exogenously applied biotin ligase), which means that it would not be useful to distinguish between agents that correct the folding of a transmembrane domain-containing protein. Thus, labeling the intracellular loop cannot be used to identify agents as recited.

Claim Rejections - 35 USC § 103

Rejection of claims 7-8 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 8/08/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that a general incentive, such as the precise labeling of CFTR instead of labeling all surface glycoproteins, does not make obvious a particular result. The Examiner asserts that the specific labeling of Schatz et al is not a general incentive, it is an incentive specific to the use of the biotin tag, and the tag is revealed in Schatz. One can specifically label recombinant proteins by including the tag in a recombinant protein. Moreover, in the case of in Re Deuel, all the limitations of the cDNA product were not disclosed in the prior art. In the instant case, all of the elements of the invention are clearly disclosed in the prior art.

Appllicant argues that Schatz does not specifically disclose how to go about labeling a cell membrane receptor such that one skilled in the art could achieve labeling of a cell membrane receptor with a reasonable expectation of success. However, the combined teachings of Schatz and Heda et al provide ample instruction and every

expectation of success. Indeed, Heda et al take advantage of the fact that glycosyl moieties are only present on extracellular domains and extracellular loops to determine what amount of CFTR has been trafficked to the plasma membrane compared to the total present. One ordinary skill could easily determine from Heda et al that the tag should go on an extracellular domain or loop.

Applicant argues that Heda et al does not measure membrane localized protein in the plasma membrane. Applicant is reminded that the title of Heda et al is, "Surface Expression of the [CFTR] mutant delta F508 is markedly upregulated by combination treatment with sodium butyrate and low temperature." The phrase "surface expression " is the same as measuring the amount of protein localized in the plasma membrane, since the plasma membrane is on the surface of the cell. Furthermore, Heda et al disclose "surface biotinylation" in the Experimental section (page 660), which is the means by which only surface receptors (in the plasma membrane) are biotinylated. This is used to measure the amount of surface expression.

Applicant also argues that Heda et al does not disclose the permeabilizing agents used in the instant specification. However, Heda does disclose the use of a permeabilizing agent. Applicant is reminded that limitations in the specification are not to be imported into the claims by the Examiner. See MPEP § 2111, in the discussion of In re Prater, 415 F. 2d 1339, 1404-05, 162 USQP 541, 550-551 (CCPA 1969).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Janet Andre can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven Standley, Ph.D.
1/16/07

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER